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IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP, formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Hatch-Waxman Act provides a pathway and financial incentives for a manufacturer of generic drugs to enter the market by obtaining a judicial determination that the brand drug maker's patent is invalid or not infringed. Brand firms can prevent or delay generic entry by paying the generics to forgo judicial review of the patents. In the case below, the Second Circuit held that, absent fraud on the patent office or sham litigation, such payments do not violate the Sherman Act, however weak the patent and even if the agreement delays generic entry until the patent expires.

The question presented is whether, absent patent fraud or sham litigation, a brand drug maker's substantial payment to a competing generic drug maker to forgo judicial testing of the patent and restrict entry is per se lawful under the Sherman Act.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 14.1(b), Petitioners state that all parties to the proceedings below appear in the caption of the case on the cover page.[1]

Pursuant to Supreme Court Rule 29.6, Petitioners state that Petitioner Louisiana Wholesale Drug Company, Inc. does not have a parent corporation and no publicly held corporation owns 10% or more of its stock. Petitioner CVS Pharmacy, Inc. is a wholly-owned subsidiary of CVS Caremark Corporation, a publicly traded corporation. No publicly held corporation owns 10% or more of CVS Caremark Corporation's stock. Petitioner Rite Aid Corporation is a publicly traded corporation. The Jean Coutu Group (PJC), Inc. is the only publicly held corporation that owns 10% or more of Rite Aid Corporation's stock. Petitioner Arthur's Drug Store, Inc. does not have a parent corporation and no publicly held corporation owns 10% or more of its stock.

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1. The Second Circuit transferred one of three consolidated appeals, 05-2863, to the Federal Circuit on November 7, 2007. Although the transferred appellants remained in the Second Circuit caption, they were not parties to the Second Circuit appeal at the time the decision was rendered. The transferred appellants were Arkansas Carpenters Health and Welfare Fund, Maria Locurto, Paper, Allied-Indus, United Food and Commercial Workers Union-Employer, Sol Lubin, Ann Stuart and Linda K. McIntrye.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 9a-35a) is reported at 604 F.3d 98. The denial of the rehearing en banc (Pet. App. 1a-8a) is not yet published but is electronically reported at 2010 WL 3464382. The district court's order granting Respondents' summary judgment motions (Pet. App. 36a-110a) is reported at 363 F. Supp. 2d 514.

JURISDICTION

The judgment of the court of appeals was entered on April 29, 2010. Rehearing en banc was denied on September 7, 2010. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant portions of the Sherman Antitrust Act, 15 U.S.C. § 1; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360cc, 35 U.S.C. §§ 156, 271, 282) (the "Hatch-Waxman Act" or the "Act"); the Patent Act, 35 U.S.C. §§ 1 et seq.; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) (the "Medicare Modernization Act"), are set out in an appendix to this petition.

INTRODUCTION

This case involves one of the most controversial business practices in the United States in one of the most important segments of our economy. Makers of branded pharmaceuticals are today routinely — 15 to 20 agreements every year — paying generic drug manufacturers not to challenge the validity of pharmaceutical patents and to delay entering the market. These agreements are annually costing consumers and taxpayers billions of dollars.

This Court has repeatedly "emphasiz[ed] the necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid." *Edward Katzinger Co. v. Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947). The Second Circuit nevertheless held, contrary to the decisions of three other circuits and the views of the United States and the Federal Trade Commission, that, except in very limited circumstances, a pharmaceutical patentee may lawfully pay a generic drug manufacturer to forgo judicial testing of the patent's validity and stay out of the market. The Second Circuit's decision cannot be squared with those of other circuits or with this Court's prohibition on patentees "muzzling" those who otherwise would have an "economic incentive to challenge the patentability of an inventor's discovery." *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

This issue has repeatedly arisen, and continues to arise, in the context of patent litigation under the Hatch-Waxman Act. The Act was intended to promote

consumer welfare by balancing incentives for brand manufacturers to innovate against protections for consumers from unwarranted patent-based monopolies. The Act extends the effective term of pharmaceutical patents, but provides a financial incentive and streamlined procedures for manufacturers of generic drugs to enter the market by contesting patent validity or infringement in court. *See, e.g.*, 21 U.S.C. §§ 355(j)(2), 355(j)(5)(B)(iv). The Act relies on judicial testing in patent litigation to ensure that monopolies created by the extended patents are legitimate and thus in fact promote consumer welfare.

The increased patent litigation prompted by the Act revealed that many patent-based monopolies in the pharmaceutical industry are not in fact warranted. From 1992 to 2001 generics won 73% of the Hatch-Waxman cases litigated to conclusion. Pet. App. 31a n.7. With huge sums at stake, however, brand manufacturers began paying generics to concede patent validity and infringement and to waive or delay entry into the market. These payoffs from the brand to the generic have been referred to as "reverse payments," because they are cash payments from the plaintiff in the infringement action to the defendant, or as "exclusion payments" or "pay-for-delay payments" because they are made in exchange for forgoing judicial examination and restricting market entry.

In the late 1990s, the FTC obtained several consent decrees against manufacturers that had paid or accepted exclusion payments. The first courts of appeals to rule on the issue concluded that the payments are anticompetitive, explaining that the brand will pay the

generic only if the patent is otherwise not likely strong enough on its own to prevent the generic from entering the market: if the patent were strong enough to prevent entry, the brand "would not have paid [the generic] $89 million to effect what the patent and infringement suit had already accomplished." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004); *see also Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (same), *cert. denied*, 535 U.S. 931 (2002).

In the early 2000s, Congress considered legislation to prohibit exclusion payments, but stayed its hand after pharmaceutical industry representatives testified that remedial legislation was unnecessary because exclusion payment settlements "would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not." *See* Pet. App. 4a & n.4. Congress therefore solved the problem of exclusion payments — or so it thought — by amending the Act in 2003 to require manufacturers to report exclusion payment agreements to the FTC and the Department of Justice (*see* Medicare Modernization Act, Title XI, Subtitle B, §1112) so that the agencies could "do[] the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws." 148 CONG. REC. S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch).

After Congress acted, however, the circuits became fractured on the standard for antitrust plaintiffs to prove that exclusion payments are anticompetitive, with courts affording the agreements increasingly lenient

antitrust treatment. The D.C. Circuit, Sixth Circuit, and the FTC had all concluded that the fact that the brand paid the generic was itself strong economic evidence that the payment resulted in less competition than the litigants themselves believed was likely to result from the patent litigation — otherwise, the brand would not have made the payment. The circuit split first developed when the Eleventh Circuit ruled that the lawfulness of an exclusion payment is determined by relitigating the patent issues as part of the antitrust case. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). The current three-way split occurred when a panel majority of the Second Circuit relied on the Patent Act's rebuttable presumption of patent validity (35 U.S.C. § 282) to conclude that, absent proof that the patent was obtained by fraud or the patent suit was a sham, the court analyzing the antitrust claim must conclusively presume that the brand manufacturer would have won the underlying patent litigation, and therefore that the exclusion payment was not anticompetitive. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007).

The *Tamoxifen* panel acknowledged that, if exclusion payments are permissible, brands will use them routinely to protect even "fatally weak" patents. *Id.* at 211. Indeed, after the *Tamoxifen* decision in late 2005, 20 of the next 27 settlements between brands and generics used exclusion payments to restrict generic entry. Pet. App. 33a. By protecting unwarranted patent-based monopolies from judicial review, these exclusion payment settlements have already cost consumers and

taxpayers more than $12 billion, and threaten to cost another $3.5 billion annually. Pet. App. 5a & n.6.

In the present case, the brand paid the generic $398 million to acknowledge patent validity and stay out of the market for all but six months of the remaining seven-year patent term. When the case reached the Second Circuit, the United States, the FTC, 36 State Attorneys General, 86 professors of law or economics, and the major consumer rights organizations filed briefs asserting that the circuit's liability standard is unduly lenient and is causing enormous consumer harm. The Second Circuit panel here unanimously concluded that the circuit's *Tamoxifen* standard should be revisited, but that the panel was nevertheless bound to follow it. Pet. App. 26a, 31a-35a.

The Court should grant review to resolve the circuit split, reject the Second Circuit standard, require compliance with this Court's precedents that favor judicial testing of patent validity, and restore the Hatch-Waxman Act balance by prohibiting brand manufacturers from paying competitors to forgo judicial examination of patents and thereby preserve unwarranted monopolies.

STATEMENT OF THE CASE

Respondent Barr Laboratories submitted a Paragraph IV Certification[1] under the terms of the

1. Such a Certification asserts that the patent on the brand drug "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Hatch-Waxman Act, asserting that the patent on Respondent Bayer Corporation's ("Bayer") best-selling antibiotic, Cipro, was invalid and unenforceable. Pet. App. 40a. In Bayer's ensuing patent suit, its motions for summary judgment were denied and the case was scheduled for trial. *Id.* at 41a. Bayer knew there was a "substantial question" as to the patent's validity, and Barr[2] had additional significant defenses of unenforceability due to inequitable conduct. If Barr won the patent case, the opening of the market to generic competition would have generated enormous savings for consumers. *Id.* at 50a. Bayer estimated that a loss in the patent case and the ensuing price competition would cause it to lose more than $1.6 billion in monopoly profits. *Id.*

Shortly before trial, Bayer and Barr settled. In exchange for Barr's agreement to confess judgment and stay out of the market for all but six months of the remaining patent term, Bayer agreed to pay Barr quarterly payments totaling $398 million. *Id.* at 42a. Alternatively, Bayer had the option to grant Barr a license to enter the market for six of the remaining seven years — a license that would have brought hundreds of millions of dollars in savings to consumers. *See id.* at 42a, 50a. Rather than permit this competition, Bayer elected under the agreement to pay Barr the $398 million, which was roughly one to two times the amount

2. Respondents Hoechst Marion Roussel and the Rugby Group, which was later acquired by Respondent Watson, contracted with Barr to share the patent litigation expenses and any resulting profits from sale of generic Cipro, and were also signatories to the challenged exclusion payment agreement. For convenience, we refer to Barr and HMR/Rugby collectively as "Barr."

Barr would have earned by winning the patent case and competing in the market.

Petitioners, direct purchasers of Cipro, filed claims against Bayer and Barr for money damages, asserting that the exclusion payment agreement violated Section 1 of the Sherman Act.[3] In opposition to Respondents' motions for summary judgment, and in support of their own motions for partial summary judgment, Petitioners offered evidence, under the rule of reason, that the six months of competition that resulted from the $398 million payment was less competition than was likely to have occurred absent the payment. This evidence included:

First, economic evidence that the payment resulted in less competition than Bayer and Barr themselves expected the patent litigation to yield, given their views of the patent's strength. If the exclusion payments did not bring less competition than both Bayer and Barr expected, one or both of them would have chosen to

3. The district court proceedings also included the claims of a putative class of indirect purchasers of Cipro. Those plaintiffs, unlike Petitioners, asserted a claim that Bayer committed fraud in obtaining the patent from the Patent and Trademark Office — a claim that the Second Circuit held "arises under" the patent laws and is thus within the exclusive appellate jurisdiction of the Federal Circuit. The Second Circuit transferred those plaintiffs' appeal to the Federal Circuit while retaining jurisdiction over Petitioners' appeals. Pet. App. 20a. The Federal Circuit affirmed the grant of summary judgment against those plaintiffs. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied sub nom. Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009). *See infra* at 20-21.

litigate rather than settle. *See* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758-59 (June 2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391, 394-95 (Summer 2003).

Second, this economic evidence was confirmed by the terms of Respondents' agreement, which provided that Bayer must give Barr either $398 million and a license to enter for six months, or a license to enter for six years. These alternative contract terms demonstrate "with unusual clarity" that exclusion payments buy the absence of competition that otherwise would likely have resulted from the patent case. Brief for the United States ("U.S. Br.") at 24 (2d Cir. July 6, 2009).

Third, deposition testimony confirmed that Barr demanded to receive in settlement an "overall value" commensurate with its view of the patent's strength. Barr demanded receipt of this value either through a license allowing it to compete in the market or through cash payments in exchange for not competing. Likewise, Bayer calculated how much to pay Barr based on a detailed expected-value analysis based on the patent's strength.

Petitioners did not — and do not — allege that it is unlawful for patent litigants to settle Hatch-Waxman cases. Litigants routinely and lawfully settle patent cases through licenses that permit the alleged infringer to enter the market before the patent expires. The patentee gauges the patent's strength and offers to give a license for, say, five years of the remaining ten-year term. The alleged infringer also gauges the patent's strength and may accept the five-year license.

These licensed-entry settlements, like exclusion payment settlements, avoid authoritative judicial testing of patents. The former generally do not violate the Sherman Act, however, because judicial testing of patents is not an end in itself, but a means of eliminating unwarranted patent-based monopolies. *See, e.g.*, *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971); *Lear*, 395 U.S. at 670. Absent an exclusion payment, settlement via a license eliminates the monopoly to the extent dictated by the patent's strength: competition occurs, and consumers benefit, for a period of time determined solely by the patent litigants' respective views of the patent's strength. Licensed entry, without exclusion payments, thus mirrors the risk-adjusted outcome of the patent litigation. *See* Hovenkamp, *Anticompetitive Settlement*, 87 MINN. L. REV. at 1758-59; Shapiro, *Antitrust Limits*, 34 RAND J. OF ECON. at 397-99.

Exclusion payment settlements are entirely different. If the patent's strength would have dictated, say, a five-year license, the generic will accept instead an exclusion payment that gives it at least five years' worth of forgone profits (or will accept a fig-leaf six month license plus a payment equal to at least 4.5 years' profit). The brand and generic avoid five years of expected competition and divide the eliminated consumer savings between themselves. In contrast, limiting the "coin" of settlement to licensed entry ensures that the generic will agree to stay out of the market for a period of time determined solely by the strength of the patent, and not by receipt of a share of the preserved monopoly profits.

The district court here found "quite powerful" the basic economic fact that "the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment." Pet. App 77a-78a. The court nevertheless granted Respondents' motions for summary judgment, holding that exclusion payments are lawful under Section 1 of the Sherman Act unless the antitrust claimant proves that the underlying patent was procured by fraud or that the patent litigation was a sham. *Id.* at 79a. This result was "compelled by the presumption of validity Congress accorded patents." *Id.* at 109a. According to the court, the rebuttable presumption of validity gives the patentee "the right to exclude competition entirely for ciprofloxacin for the term of the patent," including the right to pay the alleged infringer to concede validity and stay out of the market. *Id.* at 53a.

While the district court's ruling was on appeal in the Second Circuit, that court decided another exclusion payment case — *Tamoxifen*. A divided panel in *Tamoxifen* relied heavily on the *Cipro* district court's analysis and likewise concluded that exclusion payments are lawful unless the patent was obtained by fraud or the patent claim was a sham. *Tamoxifen*, 466 F.3d at 213. The panel majority acknowledged the "troubling dynamic" of permitting exclusion payments that "inevitably protect patent monopolies that are, perhaps, undeserved," and that, indeed, protect "fatally weak" patents. *Id.* at 211, 212. But, said the majority, the rebuttable presumption of validity requires this result: in paying the generic, the brand is merely "protect[ing] that to which it is presumably entitled." *Id.* at 208.

In this case, a Second Circuit panel affirmed the grant of summary judgment against Petitioners solely because the panel "is bound by *Tamoxifen*." Pet. App. 31a. The panel enumerated "several reasons why this case might be appropriate for reexamination," including the argument that the "*Tamoxifen* standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract." *Id.* at 31a-32a (quoting U.S. Br. at 14-15). Moreover, permitting patentees to prop up weak patents by shielding them from judicial scrutiny "offers no protection to the public interest in eliminating undeserved patents." *Id.* The panel also acknowledged the argument "that *Tamoxifen* runs afoul of the purpose of the Hatch-Waxman Act" by undermining its "incentive . . . for generic manufacturers to challenge presumptively valid patents." *Id.* at 30a.

Judge Pooler's dissent from the subsequent denial of Petitioners' request for en banc consideration elaborated on the panel's disagreement with *Tamoxifen*.[4] The "presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and allowing it to serve as a substantive basis

4. The two senior judges on the panel could not participate in deciding whether to grant rehearing en banc, but Judge Pooler reported that "the panel opinion endorses the views expressed in" her dissent from the denial of en banc rehearing. Pet. App. 3a n.1.

to limit the application of the Sherman Act." *Id.* at 6a (quoting U.S. Br. at 6-7). The Second Circuit standard is also "plainly inconsistent with the stated purpose of the Hatch-Waxman Act, which is to encourage patent challenges as a way of increasing consumer access to low-cost drugs." Pet. App. 6a. The standard "unambiguously deserves reexamination," the "'enormous importance' of the issues that this case raises is beyond dispute," and the Supreme Court should "resolve the conflict among the Courts of Appeals." *Id.* at 8a.

REASONS FOR GRANTING THE PETITION

I. The Court Should Grant Review Because the Circuit Courts Are Divided Over the Standard for Evaluating Whether Exclusion Payments Are Anticompetitive.

The circuits are split three ways over the proper standard for determining whether an exclusion payment is anticompetitive. The Sixth and D.C. Circuits hold that the fact that the brand made a payment to the generic is substantial economic evidence that, in the litigants' view, the patent was not strong enough on its own to prevent competition. The Eleventh Circuit determines whether an exclusion payment is anticompetitive by requiring that the patent issues be relitigated as part of the antitrust case. The Second Circuit relies on the rebuttable presumption of patent validity, unless there was fraud on the PTO or sham litigation, to conclude that the patentee would have won the patent case and therefore the exclusion payment is not anticompetitive.

A plaintiff makes a prima facie case of anticompetitive conduct under Section 1 of the Sherman Act by producing evidence that the challenged agreement resulted in less competition than was likely to occur absent the agreement. *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 240-41 (1918). The proper standard for determining whether exclusion payments are anticompetitive — whether they result in less competition than was otherwise likely to occur — must account for three statutory regimes: (1) the Sherman Act, which has long prohibited incumbent manufacturers from paying competitors not to enter a market, including when potential economic or legal barriers make it uncertain whether the competitor would have been successful in entering, *see, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 48-49 (1990); XII Hovenkamp, ANTITRUST LAW ¶ 2030b at 213 (2d ed. 2005); (2) the Patent Act, which includes a rebuttable presumption of validity, but depends on judicial review to prevent unwarranted patent-based monopolies, *e.g., Blonder-Tongue Labs*, 402 U.S. at 343; and (3) the Hatch-Waxman Act, which includes a statutory incentive for generics to enter the market by means of contesting patent validity or infringement in court, 21 U.S.C. § 355(j)(5)(B)(iv). The circuit split is over the proper standard, given these statutory mandates, for an antitrust plaintiff to prove that an exclusion payment resulted in less competition than was likely to occur "but for" the payment.

Sixth Circuit/D.C. Circuit/FTC: The Sixth Circuit, D.C. Circuit, and the FTC have adopted the "patent strength" standard, which bases the but-for amount of competition on the patent litigants' own view of the likely outcome of the litigation, as reflected in their objective

conduct. The fact that the generic demanded and the brand agreed to make an exclusion payment is strong economic evidence that, in those litigants' own judgment, the patent was not otherwise strong enough to prevent earlier generic entry. The patent strength standard recognizes that exclusion payments are "naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation." U.S. Br. at 22.

In *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the court applied the patent strength standard where the brand paid the generic to stay out of the market pending resolution of the patent litigation (the Hatch-Waxman Act automatic 30-month stay of generic entry, 21 U.S.C. § 355(j)(5)(B)(iii), had expired). Thus, *Cardizem* arose in a different factual context than here — the exclusion payment in *Cardizem* was made in exchange for the generic forgoing judicial testing of the patent in a preliminary injunction proceeding, and staying out of the market until entry of a final and unappealable judgment. But the legal issue is the same — the proper legal standard for determining whether it is anticompetitive for the brand to pay the generic to forgo the relevant judicial examination (preliminary injunction or trial on the merits) and stay out of the market for the relevant period of time (until the case conclusion or for a defined period).

Recognizing that many litigated patents are found to be invalid or not infringed, the Sixth Circuit held that a brand's patent does not create an "'impenetrable' legal

impediment" to generic entry. 332 F.3d at 914. Instead, the generic's analysis of the patent's strength may or may not cause it to "unilaterally, and legally [refrain from] bring[ing] its generic product to a manifestly profitable market." *Id.* at 915. An exclusion payment alters the generic's unilateral calculation based on the patent's strength and results in less competition than otherwise would likely have occurred: if the "independent durability of [HMRI's] patent and the validity of its infringement claim" had been sufficient on their own to exclude the generic from the market, then the brand "would not have paid [Andrx] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915. "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." *Id.* at 908. The court upheld the grant of partial summary judgment to plaintiffs as to antitrust liability, concluding that the anticompetitive consequences of the payment were so clear that they not only satisfied plaintiffs' prima facie case, but rendered the agreement per se unlawful. *Id.*

Considering the same agreement that was at issue in *Cardizem*, the D.C. Circuit had earlier also relied on the patent strength standard in reversing the dismissal of the antitrust claims of another generic competitor whose entry was blocked by the HMRI/Andrx agreement. *Andrx Pharm.*, 256 F.3d at 799. The court held that the agreement caused antitrust injury — injury of the type the antitrust laws are designed to prevent — because:

> HMRI's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. Andrx's argument that any rational actor would wait for resolution of the patent infringement suit [before entering the market] is belied by the *quid* of HMRI's *quo*.

Id. at 813. An exclusion payment thus "harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments." *Id.* (quoting 54 Fed. Reg. 42,873, 42,882-83).

The FTC applied the same standard in an administrative proceeding in *In re Schering-Plough Corp.*, F.T.C. Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). Evaluating an exclusion payment made in exchange for forgoing a final judicial decision on the merits, the FTC held that, "it is reasonable to assume that an agreed-on entry date [in an entry-license settlement], without cash payments, reflects a compromise of differing litigation expectations." *Id.* at 14. The fact that the patentee made a payment is economic evidence that the agreement resulted in less competition than the litigants themselves expected: "[i]f there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the

generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* Accordingly, evidence that the brand made a significant payment satisfied plaintiff's initial burden under the rule of reason. *Id.* at 15.

Eleventh Circuit: The Eleventh Circuit has expressly rejected the patent strength standard applied by the Sixth and D.C. Circuits and the FTC. *Valley Drug*, 344 F.3d at 1310. Instead, it determines the amount of but-for competition by engaging in an *ex-post* judicial determination of the patent issues as part of the antitrust case. *Id.* at 1312.

In *Valley Drug*, as in *Cardizem*, the 30-month stay had expired and the brand paid the generics to stay out of the market pending resolution of the patent case. The Eleventh Circuit held that antitrust analysis of exclusion payments requires "an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the Agreements reflect a reasonable implementation of these." *Id.* To determine whether it was anticompetitive for the brand to pay the generic not to try to enter the market before resolution of the patent case, "the provisions of this Agreement should be compared to the protections afforded by the preliminary injunction and stay mechanisms and considered in light of the likelihood of [the brand's] obtaining such protections. *Cf.* Hovenkamp at § 2046 ('some care must be taken to ensure that . . . the settlement . . . is not more anticompetitive than a likely outcome of the litigation')." 344 F.3d at 1312. On remand, the district court conducted an exhaustive analysis of the merits of the underlying patent case and

found the exclusion payments unlawful because "[t]he chance that the '207 patent would be held valid — an essential part of the equation for defining the legitimate exclusionary value of the patent — was not high as of [the date of the Agreement]." *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1298 (S.D. Fla. 2005).

The Eleventh Circuit subsequently reaffirmed this "patent relitigation" approach and applied it to an exclusion payment made in exchange for forgoing final adjudication of the patent. *Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). In *Schering*, which was the appeal from the FTC's order finding the Schering-Upsher agreement unlawful under the patent strength standard, the court faulted the FTC for relying on *ex ante* economic evidence of the patent's strength rather than conducting an *ex post* judicial evaluation. According to the court, the FTC, "cavalierly dismissed our holding in *Valley Drug*, stating that [an *ex-post* judicial] determination on the merits of the underlying patent dispute was 'not supported by law or logic.'" *Id.* at 1068 n.18.[5] The court reaffirmed that the but-for amount of competition should be determined by an *ex-post* judicial determination of the patent issues: "a settlement cannot [lawfully] be more anticompetitive than litigation." *Id.* at 1075. "*Valley Drug* established the law in our Circuit. . . . This alone underscores the

5. Relying on the patent strength standard, the FTC complaint counsel had argued that relitigating the merits of the patent case was unnecessary, and so had offered no independent evidence that the patent was invalid or not infringed.

need [for the court in the antitrust case] to evaluate the strength of the patent." *Id.* at 1076.[6]

The Eleventh Circuit's standard is subject to criticism because of the potential complexity and inefficiency of relitigating patent issues in an antitrust case. Moreover, deferring the patent issues into the antitrust case is likely to result in a significant temporal extension of the monopoly — the appeal of the FTC's order against the Schering-Upsher agreement was not concluded until nine years after execution of the agreement, and private antitrust claims over the agreement are still pending. Equally troubling, the generics, which have expertise in challenging pharmaceutical patents, switch sides in the antitrust case: Upsher asserted in the patent case that Schering's infringement claim was so weak as to constitute a sham, then joined with Schering in the antitrust case to argue that the infringement claim was not a sham. *See In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at *30 (D.N.J. Feb. 6, 2009).

Second and Federal Circuits: The Second and Federal Circuits have expressly rejected the Sixth/D.C. Circuit patent strength standard and have refused to apply the Eleventh Circuit's relitigation standard. *See Tamoxifen*, 466 F.3d at 203-04, 213; *Ciprofloxacin*, 544 F.3d at 1337. They have instead conclusively presumed for purposes of the antitrust case that the patent was valid, and thus that no competition was likely to result

6. The Eleventh Circuit also reversed, on the record before it, the FTC's factual finding that the brand had made a payment to the generic. *Schering-Plough Corp.*, 402 F.3d at 1071.

from the patent litigation, unless the patent was obtained by fraud or the patent claim was a sham.

As noted above, the panel majority in *Tamoxifen* concluded that this sham litigation standard is required by the rebuttable presumption of patent validity. *Tamoxifen*, 466 F.3d at 213. The Second Circuit panel here unanimously disagreed with that conclusion but felt bound to adhere to *Tamoxifen*.

The Federal Circuit considered the same agreement at issue here, at the behest of indirect purchasers of Cipro whose appeal was transferred to that circuit.[7] The Federal Circuit concluded it was required to decide the case "[u]nder the law of the Second Circuit." *Ciprofloxacin*, 544 F.3d at 1332. The court held that the rebuttable presumption of validity required adoption of the sham litigation standard, reasoning that, "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled — a monopoly over the manufacture and distribution of the patented invention. *In re Tamoxifen*, 466 F.3d at 208-09." *Ciprofloxacin*, 544 F.3d at 1337.[8]

The sham litigation standard is legally and factually insupportable. This Court has endorsed such a lenient antitrust standard only for a monopolist's unilateral, constitutionally protected conduct in petitioning the government to restrain competition. *See infra* at 32. That standard is wholly inappropriate for judging

7. *See supra* footnote 3.

8. We discuss *infra* at 33 the circumstances in which this Court declined to review the Federal Circuit's decision.

erstwhile competitors' joint conduct in withdrawing a patent dispute from judicial oversight and restraining competition by private agreement.

The sham litigation standard also ignores the commercial reality that, despite the rebuttable presumption of validity, nearly half of all litigated patents are found invalid, John R. Allison and Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 206 (1998), and that generics have won 73% of Hatch-Waxman cases, Pet. App. 31a n.17. Under the sham litigation standard, a patentee with merely a colorable claim, with, say, an 80% chance of *losing*, may lawfully pay the generic a share of the monopoly profits in exchange for staying out of the market. *Cf. Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992) ("[l]egal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law"). The rebuttable presumption of validity was designed merely to allocate burdens of proof in a patent litigation that determines *whether* the patent-based monopoly is legitimate, not to authorize the patentee to pay to prevent judicial review and thereby preserve the monopoly *regardless* of its legitimacy. As Judge Pooler noted:

> [E]ven though we are required to presume that Bayer's patent is valid, . . . "[t]he presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and

> allowing it to serve as a substantive basis to limit the application of the Sherman Act."

Pet. App. 6a (quoting U.S. Br. at 6-7). If upheld, the sham litigation standard "would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights." *Terazosin*, 352 F. Supp. 2d at 1298.

The Second Circuit's sham litigation standard conflicts with the patent relitigation standard of the Eleventh Circuit and with the patent strength standard of the Sixth and D.C. Circuits and the FTC. Under the sham litigation standard, exclusion payments are nearly per se lawful; under the patent strength standard, the fact that the brand made an exclusion payment is, at a minimum, sufficient evidence to satisfy the antitrust plaintiff's initial burden under the rule of reason, and, under the Sixth Circuit approach, renders the agreement per se unlawful. Shunning both of these standards, the Eleventh Circuit requires the patent issues to be litigated anew as part of the antitrust case. The conflict between the circuits is clear and wide.

II. The Court Should Grant Review Because the Second Circuit's Standard Conflicts with This Court's Precedents.

The Second Circuit has elevated the rebuttable presumption of validity into an ironclad right of patentees to exclude competition — a right enforceable by paying generics to forgo judicial examination of patent validity and stay out of the market. The Second Circuit's newly created right conflicts with two lines of this Court's cases.

Conflict With the Court's Patent Cases. The Second Circuit standard conflicts with this Court's patent cases, which emphasize that a patentee's right to exclude competitors is limited and qualified, and that "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 58 (1973) (citation omitted). "A patent by its very nature is affected with a public interest" because of its potentially "far-reaching social and economic consequences." *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). Consequently, the alleged infringer's right to challenge the patent's validity in court "is not only a private right to the individual, but it is founded on public policy, which is promoted by his making the defense, and contravened by his refusal to make it." *Edward Katzinger Co.*, 329 U.S. at 401 (citation omitted).

The Second Circuit asserted that it had safeguarded the public interest by limiting the exclusion effected by the brand's payments to the subject matter and temporal scope of the patent, assuming that the patent is valid. *Tamoxifen*, 466 F.3d at 213-14. But under this Court's precedents, the requirement that exclusion not exceed the subject matter or temporal scope of the patent is just "one obvious manifestation" of the public interest in patents. *Blonder-Tongue Labs*, 402 U.S. at 343. The Second Circuit ignored a second aspect of this interest — "[a] second group of authorities [that] encourage authoritative testing of patent validity." *Id.*

at 344.[9] Although patents carry a rebuttable presumption of validity, "Congress has from the outset chosen to impose broad criteria of patentability while lodging in the federal courts final authority to decide that question." *Id.* at 332.

Accordingly, this Court has repeatedly emphasized that judicial testing of patent validity is essential precisely because the issuance of a patent by the PTO was not intended to have — and does not have — the conclusive significance accorded by the Second Circuit:

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.

Lear, 395 U.S. at 670.

This Court has held, for example, that requiring patent licensees to continue paying royalties as a prerequisite to challenging patent validity would

9. We again note that this does not mean that litigants should be precluded from settling Hatch-Waxman patent cases. The purpose of judicial testing of patent validity is to protect consumers from unwarranted patent-based monopolies. Licensed entry settlements, unlike exclusion payment settlements, eliminate monopolies — and benefit consumers — to the extent dictated by the strength of the patent. *See supra* at 10.

impermissibly "muzzle[]" those who otherwise have an "economic incentive to challenge the patentability of an inventor's discovery." *Id.*; *see also Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (federal courts have jurisdiction to decide patent validity even when parties are complying with license terms). Permitting brands to simply pay generics to forgo judicial testing of patents is the antithesis of "protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid." *Edward Katzinger Co.*, 329 U.S. at 400.

This Court also held that it is "inconsistent with the aims of federal patent policy" to permit patentees to "postpone the day of final judicial reckoning." *Lear*, 395 U.S. at 673; *see also Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83, 101 n.24, 102 (1993) (prohibiting practice of vacating declaratory judgments of invalidity because it improperly "multipl[ies] the opportunities for holders of invalid patents" to try to enforce them and "prolongs the life of invalid patents"). Permitting the brand to pay the first generic challenger to forgo judicial review delays challenges by other generics. "The regulatory scheme for pharmaceutical patents [*i.e.*, the 30-month Hatch-Waxman stay of generic entry] means that by settling with an ANDA filer, a patent owner can delay entry by any other generic for three years or more." Herbert Hovenkamp, et al., IP AND ANTITRUST, §15.3 at 15-45 (2d ed. 2010). For example, here subsequent challengers to the Bayer patent did not even get to the summary judgment stage until over four years after the Bayer/Barr trial was to have begun. *See Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002). And as is often

the case, this not only delayed, but also reduced the potency of, those subsequent challenges. Given the imminent expiration of the Bayer patent, the delayed subsequent challengers waived all fact-intensive defenses to Bayer's patent, with the result that the best defenses that Barr intended to pursue at trial have never been litigated. *See* Plaintiffs-Appellants' Brief at 15 (2d. Cir. May 5, 2008). *See also Tamoxifen*, 466 F.3d at 194 (exclusion payment settlement was contingent on vacatur of district court judgment finding patent invalid). The Second Circuit standard permits the patentee to buy multiple opportunities and to unfairly tilt the litigation landscape in the very ways this Court has condemned as against public policy.

The Second Circuit standard also disregards this Court's critical distinction between a patentee's substantive right to exclude competition and the limited, qualified remedies available to the patentee to enforce that right. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006). The Court held that even after a final judgment finding infringement, the patentee is not automatically entitled to exclude the adjudged infringer, but instead must satisfy the traditional requirements for equitable relief. *Id.* at 392-93. Under *eBay*, even a patent judicially tested and found valid and infringed may not merit excluding competition; under the Second Circuit standard, wholly untested, exceedingly weak patents — all except those whose attempted enforcement would constitute a sham — merit excluding competition.

The Second Circuit standard is even less supportable when considered in light of the Hatch-

Waxman Act's statutory incentives for generics to enter the market through patent challenges. The Act provides that the first generic that challenges the patent can receive 180 days as the exclusive generic version of that product on the market. 21 U.S.C. § 355(j)(5)(B)(iv). This reward is valuable to the generic only if it enters the market and sells a low-price product to consumers. The statutory incentive was designed to bring consumer savings through generic entry, not to enrich generic firms that accept payments to forgo entry.

The Hatch-Waxman Act also precludes any notion that unreviewed patents grant an ironclad right to exclude competitors. The Act gives patentees a procedure to obtain automatic exclusion of generics — without the need to satisfy the criteria for a preliminary injunction — for up to 30 months.[10] After 30 months, however, the FDA is free to approve a generic drug for

10. The Second Circuit seemed to suggest that the Act's 30-month stay provision somehow makes exclusion payments "natural" because it prevents the generic from entering the market and amassing potential liability for infringement damages that the brand could use as a bargaining chip in settlement negotiations. *Tamoxifen*, 466 F.3d at 206-07. The idea seems to be that this reduced settlement leverage makes exclusion payments the only viable means of settling the case. But the Act does not require the brand to invoke the 30-month stay; the brand may instead renounce the stay and then try to collect damages for infringement. 35 U.S.C. § 271(a). Even when brands relinquish some settlement leverage in exchange for 30-month stays, the patent cases still can be settled without exclusion payments, and thus they "serve no obvious redeeming social purpose." Pet. App. 5a. The cases can be settled – and, until *Tamoxifen*, routinely were settled — through early-entry licenses. *See id.* at 33a.

marketing regardless of ongoing patent litigation and despite the rebuttable presumption of validity. *See* 21 U.S.C. § 355(j)(5)(B)(iii). After the 30 months, the patentee can obtain exclusion only by obtaining a preliminary injunction — a proceeding in which "the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991). Yet the Second Circuit relies on the rebuttable presumption of validity to justify the brand's obtaining the equivalent of an automatic, unreviewed, post-30-month permanent injunction through the expedient of sharing some of the monopoly profits with the generic.

Exclusion payments are plainly antithetical to the core purpose of the Act:

> [T]hrough the [Hatch-Waxman] Amendments, "Congress sought to get generic drugs into the hands of patients at reasonable prices — fast." We disagree with Andrx that "its conduct was not only permitted under but clearly contemplated by the Hatch-Waxman" Amendments. Although it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay [entry].

Andrx Pharm., 256 F.3d at 809 (citations omitted); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067 (D.C. Cir. 1998) (collusion between brand and generic

manufacturers is "at odds with Congress's apparent purposes, in enacting [the Act], of rewarding innovation and bringing generic drugs to market quickly").[11]

This Court has repeatedly emphasized the policy in favor of judicial examination of patent validity as a means of protecting consumers from unwarranted patent-based monopolies. The Hatch-Waxman Act specifically incentivized patent challenges in this sector of the economy where unwarranted monopolies cause grievous consumer harm. The Second Circuit standard allows patentees to countermand the statutory incentive and buy a shield from judicial examination of the legitimacy of their patents.

Conflict With the Court's Antitrust Cases. The Second Circuit standard also violates this Court's fundamental antitrust principles. For more than a century, this Court has held that it is anticompetitive for a firm to pay a competitor to exit or stay out of the market. *See, e.g., United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899); *United States v. Topco Assocs., Inc.*, 405 U.S.

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11. *See also Terazosin*, 352 F. Supp. 2d at 1298 (sham litigation standard "would give the patent holder rights beyond those granted by the Patent Act, and beyond the structure contained in the Hatch-Waxman Act"); C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1614-16 (2006) ("The Hatch-Waxman Act's calibration between innovation and competition is disrupted if firms are free to engage in self-help. The resulting disruption is difficult to square with the policies that animate the Hatch-Waxman Act. . . .").

596, 608-09 (1972). Paying competitors not to enter is anticompetitive even when potential entry barriers — whether economic or legal — make it uncertain whether the competitor's attempt to enter would have succeeded. *See, e.g., Palmer*, 498 U.S. at 48-49; *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc); XII Hovenkamp, ANTITRUST LAW ¶ 2030b at 213 (2d ed. 2005). "Such agreements are anticompetitive regardless of whether the parties split a market within which both [currently] do business. . . ." *Palmer*, 498 U.S. at 49.

A patent is a potential entry barrier, and this Court has never afforded patentees antitrust immunity for paying competitors not to try to overcome them. The Second Circuit derived its patent fraud/sham litigation standard from this Court's decisions in *Walker Process Equip., Inc. v. Ford Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965), and *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). But those cases provide the standard for imposing antitrust liability on a monopolist's constitutionally protected conduct in petitioning the government to restrain competition by granting and enforcing a patent. An exclusion payment settlement withdraws such a petition from the government and instead restrains competition by private treaty. This private conduct enjoys no immunity warranting such a lenient antitrust standard. *See, e.g., Federal Trade Comm'n v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 424-25 (1990) (immunity applies only when "the alleged restraint of trade [is] the intended consequence of public action"). A patentee that makes exclusion payments helps itself to guaranteed exclusion that government procedures simply do not provide:

> What the pharmaceutical patentees who agree to exclusion payments seek is something more [than the legitimate exclusionary power of the patent] — a guaranteed insulation from competition, without the risk that the patent is held invalid. IP policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors.

Hovenkamp, *Anticompetitive Settlements*, 87 MINN. L. REV. at 1761-62.

Moreover, *Walker Process* and *PRE* provide the standards for imposing antitrust liability on a defendant's *unilateral* conduct in obtaining and enforcing a patent. But making and accepting an exclusion payment is collusive, not unilateral; it combines the economic interests of two competitors whose unilateral interests were previously to affirm, and to deny, respectively, the patent's validity. This Court's precedents apply significantly more stringent antitrust standards to collusive than to unilateral conduct. *See, e.g., Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *accord United States v. Singer Mfg. Co.*, 374 U.S. 174, 199-200 (1963) (White, J., concurring) (settlement of patent interference was unlawful because it was not "purely unilateral action" but instead reflected "collusion among applicants to prevent prior art from coming to or being drawn to the [PTO's] attention"). The Second Circuit standard would impose antitrust liability on exclusion payment agreements only when the patentee's request that the government restrain

competition would itself be unlawful under Section 2 of the Sherman Act; the standard accords no independent antitrust significance to a patentee's payment to a competitor to forgo having a court decide whether the patent meets the statutory requirements and whether restraining competition is in the public interest.

III. The Court Should Grant Review Because This Case Is the Right Vehicle to Resolve This Recurring Issue of Enormous Public Importance.

This case is the right vehicle for the Court to resolve the circuit split and require compliance with the Court's antitrust and patent precedents. The Court has previously denied certiorari in a number of exclusion payment cases. This case, however, does not suffer from any of the procedural impediments that may have counseled against using those prior cases to resolve these issues whose "'enormous importance' . . . is beyond dispute." Pet. App. 8a.

In both *Tamoxifen* and the Federal Circuit's decision in *Ciprofloxacin*, the petitioners were indirect purchasers who could not recover damages under federal antitrust law, *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), and whose federal claims for injunctive relief had been rendered moot by the expiration of the patents. Brief for the United States as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 at 17 (S. Ct. May 2007) (advising Court that petitioners' claims were moot); Brief for Bayer, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, No. 08-1194 at 18 (S. Ct. May 22, 2009) (same). Petitioners here have live federal antitrust claims for damages.

When the Eleventh Circuit's adoption of the patent relitigation standard first caused the circuit split, the United States recommended against review because of, *inter alia*, a threshold factual dispute in that case as to whether the brand had made any payment to the generic. Brief for the United States as Amicus Curiae, *Federal Trade Comm'n v. Schering-Plough Corp.*, No. 05-273 (S. Ct. May 2006).[12] The brand had agreed to pay royalties to the generic ostensibly for use of some of its technology, and the threshold issue was whether this was an above-market-price agreement that was in reality a disguised exclusion payment, or was instead a bona fide royalty agreement. *Id.* at 12-13.

A comprehensive analysis of all known exclusion payment settlements has concluded that all recent agreements, unlike the one at issue here, have taken the form of a disguised payment from the brand to the generic, similar to the one used in *Schering*. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649 (2009). Thus, every antitrust case premised on those exclusion payments will present a threshold factual question of whether the brand made a payment to the generic. *See, e.g., In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1375 (N.D. Ga. 2010) (alleging disguised payment

12. The United States also disagreed with the FTC on the merits of that case. U.S. Br., *Schering-Plough Corp.*, No. 05-273 at 11-12. In contrast, the United States has consistently argued that the Second Circuit standard is "incorrect" and "insufficiently stringent." U.S. Br., *Joblove*, No. 06-830 at 1, 8; *see also* U.S. Br. at 6 (quoting *Tamoxifen*, 466 F.3d at 224 (Pooler, J., dissenting)).

in form of above-market-price contract); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d. 514, 522-23 (E.D. Pa. 2010) (same); *K-Dur*, 2009 WL 508869 at *7 (same).

The problem of exclusion payments and the proper liability standard is not abating — manufacturers used at least forty exclusion payment agreements to restrict generic entry in the last two years. This case provides the Court with its best opportunity to resolve the circuit split over the appropriate legal standard without having to address it in the context of a factual dispute as to whether a complex commercial arrangement between the brand and generic is actually a disguised exclusion payment. Hemphill, *An Aggregate Approach to Antitrust*, 109 COLUM. L. REV. at 663.

The question of the proper standard for determining whether an exclusion payment is anticompetitive has been percolating in the courts, and thoroughly debated in academia, for over a decade. The three potential standards that have emerged are reflected in the three-way circuit split. This case presents the best opportunity for the Court to resolve the circuit split, require compliance with the Court's patent and antitrust precedents, and restore the Hatch-Waxman Act balance between extending pharmaceutical patent terms and preserving judicial review of those patents to ensure that the resulting monopolies are warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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